35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative history of anything contrary to this interpretation as support for their position that "and" means "or". Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

Applicants respectfully traverse the Restriction of Groups I and II. The Examiner does not assert that the inventions of the claim groups listed above are independent. Rather, the Examiner alleges that the inventions of the claim groups listed above are distinct because the product of Group I "can be made recombinantly or made by chemical peptide synthesis."

Applicants assert that restriction is improper because the Examiner's rationale for restricting Groups I and II does not satisfy the requirements of MPEP 806.05(f). In particular, Applicants respectfully note that the product of Group I is a composition comprising a heterodimeric insulin complex that is formed by a process of combining a first insulin species with a second insulin species (which is the process of Group II). In this context, while Applicants acknowledge that polypeptides can be made by different processes (e.g. recombinantly or via chemical peptide synthesis), **this observation simply does not support the Examiner's assertion** that a composition comprising a first insulin species and a second insulin species (e.g. claims 1-14) can be made by a process that is different from a process comprising combining a first insulin species with a second insulin species (e.g. claims 15-27). For this reason alone the restriction between Groups I and II should be withdrawn.

Applicants further urge the Examiner take into consideration that the subject matter of claim Groups I and II is linked by this common inventive concept.

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met.

Applicants assert that a search into prior art with regard to the invention of the different groups is so related that separate significant search efforts should not be necessary. For example, a

search finding that a composition comprising a first insulin species and a second insulin species, wherein the first insulin species and the second insulin species form a heterodimeric complex; and wherein the first insulin species and the second insulin species are selected such that the heterodimeric complex is more stable than a homodimeric complex formed by the first insulin species or a homodimeric complex formed by the second insulin species is novel and nonobvious should provide the necessary information for examination of a method of making an insulin composition, comprising combining a first insulin species and a second insulin species, wherein the first insulin species and the second insulin species form a heterodimeric complex; and wherein the first insulin species and the second insulin species are selected such that the heterodimeric complex is more stable than a homodimeric complex formed by the first insulin species or a homodimeric complex formed by the second insulin species without requiring an additional search effort. Accordingly, there is no serious burden on the Examiner to collectively examine claim Groups I and II. Therefore, restriction is not proper under M.P.E.P. §803.

Consequently, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement between Groups I and II and to examine claims 1-27 collectively. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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